REMARKS

This Amendment and Response is in reply to the Non-Final Office Action mailed January 13, 2004. Claims 11-26 have been previously cancelled. Claims 1-10 and 27-35 were rejected. With this Response, claims 1-7, 10, 27-28, and 31-34 have been amended and claims 29-30 and 35 are cancelled. New claims 36-43 are added. Accordingly, claims 1-10, 27-28, 31-34, and 36-43 are pending in the application and are presented for consideration and allowance.

Claims Rejections under 35 U.S.C. §112

In the Office Action, claim 35 was rejected under 35 U.S.C. §112, first paragraph, as containing new matter.

Applicant has cancelled claim 35, therefore obviating the rejection.

Claim Rejections under 35 U.S.C. §102

In the Office Action, claims 1-10 and 27-30 were rejected under 35 U.S.C. §102(b) as being anticipated by Stylli et al. U.S. Patent No. 5,985,214 (herein "Stylli") and claims 1, 31-34 were also rejected under 35 U.S.C. §102(b) as being anticipated by Stylli.

Applicant's independent claim 1 specifies an automated method for analyzing substances containing cellular material. The method comprises activating a test apparatus having at least one liquid ejection device acting in cooperation with an electronically actuated printhead to dispense a first defined volume from the at least one liquid ejection device. The first defined volume contains at least one potential pharmaceutically active agent and is dispensed into contact with at least one defined volume of a substance containing a target cellular material wherein the target cellular material is at least one of whole cells and recognized cellular components from intact cells. The method also comprises detecting in the at least one defined volume a pharmacological effect on the target cellular material triggered by introduction of the first defined volume of the at least one potential pharmaceutically active agent. Information is generated that is indicative of the effect of the at least one potential pharmaceutically active agent on the cellular material and then analyzed to generate a correlation factor of the relative effectiveness of the agent on the target cellular material.

Stylli discloses using targets for identifying chemicals that are useful in modulating the activity of a target. The target can be any biological entity, such as a protein, sugar, nucleic acid, or lipid. Typically, targets will be proteins such as cell surface proteins or enzymes. Targets can be assayed in either biochemical assays (targets free of cells), or cell based assays (targets associated with a cell). See Stylli Column 39, lines 1-9. Targets are also identified as including proteins, such as membrane proteins and soluble proteins, and may include those from genomics and unspecified targets. See Stylli Column 38, lines 10-14.

It appears that Stylii does not contemplate that the whole cell itself, or cellular components from intact cells would be the target. Rather Stylli extensively discusses cell-based assays, apparently focusing on how the cell surface or components can assist in identifying a target, such as a protein, that is not the cell or a cellular component. See Stylli at Column 38, lines 14-31, which discloses dispensing an assay solution containing an agonist, antagonist that interacts with the target . . . and discloses that activity is often measured from a reporter that indirectly or directly indicates the activity of the chemical against the target. Specific examples of cells acting as part of assays and acting as reporters, not targets, are detailed in Columns 38 and 39 of Stylli. Accordingly, these cell-based assays disclosed in Stylli help test targets, but the cells in the assay are not the targets themselves.

Using cell-based assays as part of high throughput screening to identify proteins, such as with genomics of the type of activity in Stylli is not equivalent to analyzing a pharmacologic effect on target cells and target cellular material triggered by applying a potential pharmaceutically active agent, in an automated method as claimed by Applicant which includes generating information indicative of the pharmacologic effect on the target cellular material (e.g., whole cells, and cellular components from intact cells) and analyzing that information to determine a correlation factor of the relative effectiveness of the at least one potential pharmaceutically active agent.

As apparent from the complexity and scale of operation in Stylli, Stylli is directed to high throughput screening for mass screening of targets, such as proteins, and the use of cells as vehicles in assays for testing the targets. Again, Stylli concern for pharmaceutical compositions focuses on storage and subsequent administration, see Stylli Column 43, lines 45-47, and **not** on evaluating pharmacologic effect of pharmaceutical agents on **cells as targets,** as specified in Applicant's claimed automated method in independent claim 1.

For these reasons, Stylli does not anticipate or make obvious Applicant's independent claim 1, which is therefore believed to be patentable over Stylli. Applicant's claims 2-10, 29-30, and 31-34 are believed to be patentable based on their dependency from claim 1.

Moreover, Applicant's dependent claims, including claims 2 and 10 are believed to be patentable for reasons in addition to the patentability of independent claim 1.

Applicant's claim 2 specifies an automated method of analyzing substances including, in part, a cartridge removably associated with a liquid ejection device for containing at least one potential pharmaceutically active agent. In contrast, Stylli discloses a much more cumbersome, complex array of chemical wells from which liquid is to aspirated from before a liquid dispenser dispenses an agent. In particular, even Stylli's disclosure of nanoliter dispensers at Column 16, lines 30-50, do not describe (nor illustrate) a cartridge removably associated with a liquid ejection device that has an interior chamber defining a fixed volume for containing the at least one potential pharmaceutically active agent. Rather, Stylli discloses a liquid dispenser that obtains liquid, via a reservoir, aspirated from an addressable chemical well of a vast array of chemical wells. See Stylli at Column 16, lines 30-33. Accordingly, Stylli does not anticipate or make obvious Applicant's claim 2.

Applicant's claim 10 specifies interactively activating at least one second liquid ejection device in cooperation with an electrically actuated printhead to dispense a second defined volume of a potential pharmaceutically active substance into contact with the at least one defined volume of the substance containing target cellular material. In contrast, Stylli merely discloses an "interface for generating specific liquid dispensation patterns and volumes to the high density plate". This assertion based on Stylli does not address the limitations in Applicant's claim 10. This general identification of a "dispensation pattern" does not address applying a second volume of an agent to the same target substance (" the defined volume including the target cellular material"). This pattern in Stylli apparently refers generally to the spatial arrangement in which liquid is applied to a plate, not whether a second volume of an agent has been applied to the same target. In addition, the passage from Stylli "interface for generating specific . . . volumes to the high density plate" merely refers to selecting different quantities of some liquid to be applied to the plate. In specifying "dispensing a . . . second volume" in claim 10, Applicant specifies that a separate, second portion an agent (the same agent or a different agent) be applied to the same defined volume

of target cellular material, i.e., the same target not different targets. In contrast, Stylli broadly asserts that different amounts of liquid (i.e., quantities or "volumes") can be dispensed on the plate.

Moreover, the broad assertion in the Office Action regarding Stylli (citing Column 33, lines 30-48) of using multiple dispensers to apply multiple reagents also does not address the limitations of Applicant's claim 10, i.e., that a second volume is applied to the same ("at least one defined volume") target cellular material to determine a pharmacologic effect. Rather, this passage from Stylli merely states that a lot of agents are available and that there can be different dispensers for dispensing the different agents. At no time does this passage from Stylli address evaluating the target material by making a second application of an agent to that same sample (including one or more same samples) of target material, as achieved with Applicant's claimed method. Accordingly, in addition to the reasons for patentability of claim 1, Stylli does not anticipate or make obvious Applicant's claim 10.

For these reasons, Applicant's independent claim 1, and claims 2-10, 29-30, and 31-34 depending therefrom are believed allowable over Stylli.

Claim Rejections under 35 U.S.C. §103

In the Office Action, claims 1, 31-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stylli and Pham et al. U.S. Patent No. 6,171,780 (herein "Pham").

Applicant's claim 35 has been cancelled obviating the necessity to respond the rejection regarding the three-dimensional array.

Regarding the rejection of claims 1 and 31-34 based on Stylli and Pham, Applicant's claims 1-10, and 31-34 are believed to be patentable over Stylli for the same reasons of patentability advanced for claims 1-10 and 31-34 presented above in response to the rejection under 35 U.S.C. 102 based on Stylli.

New Claims 36-44 under Group I

Applicant has submitted new claims 36-43, which fall under Group I of prior election (Response to Restriction Requirement mailed October 29, 2002). New claims 36-43 including various limitations of claims that have been presented previously in claims 1-10,

27-35, but that have not been addressed in previous Office Actions. These claims are presented in the form of Group I (e.g., Applicant's independent claim 1) directed to an automated method for analyzing substances containing a target cellular material. Accordingly, Applicant's request favorable treatment of claims 36-43 as part of Group I, along with independent claim 1 and dependent claims 2-10, 31-34.

In addition, Applicant requests allowance of claims 36-43 over Stylli and Pham. Neither Stylli nor Pham discloses or suggests an automated method of analyzing substances in which a liquid ejection device includes a cartridge removably associated with liquid ejection device and including an interior chamber defining a fixed volume for containing at least one potential pharmaceutically active agent (dependent claim 2; new independent claim 36). Neither Stylli nor Pham discloses or suggests such an automated method of analyzing substances includes such a cartridge having a memory device in the cartridge (dependent claim 27; new dependent claim 37) or having control electronics in the cartridge (dependent claim 28; new dependent claim 38).

In addition, Applicant request favorable consideration of Applicant's new claims 41-43. New independent claim 41 specifies an automated method of analyzing substances that includes, in part, dispensing, based on generated first information, a second defined volume of at least one potential pharmaceutically active agent. New dependent claim 42 specifies, in part, that the at least one potential pharmaceutically active agent of the first defined volume differs from the at least one potential active agent of the second defined volume by at least one of type, concentration and quantity. New dependent claims 43 specifies an automated method of analyzing substances including, in part, dispensing the first defined volume from a first chamber of the cartridge, and dispensing the second defined volume from a second chamber in the cartridge separate from the first chamber.

In light of the above, Applicant believes independent claims 1, 36 and 41, and the claims depending therefrom, are in condition for allowance. Allowance of these claims is respectfully requested.

CONCLUSION

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CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 13th day of April, 2004.

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